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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,953

12/30/2005

Stefan G. Pierzynowski

CU-4618 BWH

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EXAMINER

BLAKELY III, NELSON CLARENCE

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

01/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/562,953	Applicant(s) PIERZYNOWSKI ET AL.	
	Examiner NELSON C. BLAKELY III	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 29 and 32-39.
 Claim(s) withdrawn from consideration: 7-28 and 30.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/Nelson C Blakely III/
Examiner, Art Unit 1614

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claim 38 under 35 U.S.C. 112, second paragraph, is withdrawn pursuant to Applicant's Amendment, filed 10/06/2009.

Continuation of 11. does NOT place the application in condition for allowance because: The After Final Amendment, filed 10/16/2009, is acknowledged, and entered into the record.

Claims 29, 32 and 37-39 were rejected under 35 U.S.C. 102(b) as being anticipated by Riedel et al.

Applicant's Arguments

Applicant alleges that hemodialysis patients have no particular problem in their absorption of amino acids from the gut. Further, Applicant alleges that the fact that the level of essential amino acids was increased in Riedel et al. does not suggest, let alone prove, that the uptake is increased. Applicant alleges that Riedel et al. do not draw the conclusion that the uptake of essential amino acids from the diet is increased.

Examiner's Response

Applicant's Arguments, filed 10/06/2009, have been considered, but are not persuasive. As mentioned in the previous Office Action, mailed 08/17/2009, Riedel disclose the administration of alpha-ketoglutarate in combination with the phosphate binder calcium carbonate to determine their effect on the amino acid metabolism in patients. See Abstract. In doing so, the plasma concentrations of essential amino acids such as proline and leucine increased significantly. See the last three paragraphs of the Discussion on page 264. Accordingly, a skilled artisan, at the time of the invention, would have construed "absorption" to essentially mean the change in the net amount of amino acids in a subject compared to the subject not obtaining administration. Absent evidence to the contrary, or specific language directed to a subject in need thereof, one of ordinary skill in the art, at the time of the invention, would have envisaged the administration of, at least, alpha-ketoglutarate, wherein there is an increase in the plasma concentration of the essential amino acids, e.g., proline and leucine, to meet the claims. The rejection is maintained.

Claims 29 and 32-39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Riedel et al., in view of Plouvier et al and Shiflett et al.

Applicant's Arguments

Applicant alleges Riedel et al. does not teach, disclose or suggest a method as in claim 29 of using AKG to improve the absorption of amino acids. Further, Applicant alleges that neither Plouvier et al. nor Shiflett et al. cure the deficit found in Riedel et al.

Examiner's Response

Applicant's Arguments, filed 10/06/2009, have been considered, but are not persuasive. See Examiner's Response with regard to Riedel et al. supra.

Further, Riedel et al. fail to disclose specifically wherein the invertebrate is a rodent, a farm animal or a domestic pet. However, Plouvier et al. disclose, in at least reference claim 33, a method of treating a mammal in need of treatment, said method comprising administering a therapeutically effective amount of the enteric composition of reference claim 1 to the mammal, wherein the composition comprises lysine or proline alpha-ketoglutarate, for example. In summation, Shiflett et al. discloses alpha-ketoglutaric acid use in chick, or bird, tissue. Accordingly, the rejection is maintained.